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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/493,480	01/28/00	CHEEVER M	0140580-0098

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EXAMINER	
HUNT, J	
ART UNIT	PAPER NUMBER
1642	4

DATE MAILED: 07/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/493,480	Cheever et al.
Examiner	**Art Unit**
Jennifer Hunt	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *93-116* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *93-116* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *4,6*
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group II, claims 8-9, 15-18, 33-34, 40-43, and 89-92 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that there is no undue search burden. This is not found persuasive because the claims are drawn to distinct methods and products which are classified in different groups and require non-coextensive searches for reasons set forth in the original restriction.

The requirement is still deemed proper and is therefore made FINAL.

Acknowledgment is made of applicant's cancellation of claims 1-92, and subsequent addition of claims 93-116. Claims 93-116 are pending and under consideration.

Specification

2. The use of the apparent trademark Herceptin, for example, has been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Further applicant should review the specification to ensure all trademarks are appropriately recited.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 U.S.C. § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 116 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 116 includes apparent trademarks in the recitations of "Q sepharose High Performance Columns", and "Phenyl Sepharose 6 Fast Flow low substitution". Trademarks should be capitalized wherever they appear and should be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 93-116 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 93-116 are broadly drawn to a polynucleotide of any size comprising a sequence that is at least 80% homologous to SEQ ID NO: 6, or 7, or a fusion of SEQ ID NO:3 to 4, or of 3 to 5 and the corresponding vectors, host cells, and methods of making a polypeptide. Thus claims are drawn to a polynucleotide of any size which is only defined by a small number of nucleic acid resides, hence the claims are drawn to nucleic acid residues which minimally contain only portions of SEQ ID NO:3-7. Accordingly, the claims are drawn to a large genus of molecules. In the case of small identified nucleic acid residues claimed with open language, the genus of the polynucleotides comprising a partial sequence encompasses a variety of subgenera with widely varying attributes. The specification discloses only the structural features of the species SEQ ID NO:3-7. The specification lacks information to lead one of ordinary skill in the art to understand that the applicant had possession of the broadly claimed genus of polynucleotides at the time the instant application was filed. Applicant is referred to the

guidelines 112, first paragraph, published in the Official gazette and also available on www.uspto.gov.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

7. Claims 99-102 and 109-112 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide composition comprising SEQ ID NO:6 or 7, or a fusion of SEQ ID NO:3 to 4, or 3 to 5 and the corresponding vectors, host cells, and methods of making a polypeptide, does not reasonably provide enablement for the corresponding pharmaceutical composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining scope and enablement are: 1) quantity of experimentation necessary, 2) the amount of direction or guidance presented in the specification,

3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the relative skill of those in the art, 7) the predictability of the unpredictability of the art, and 8) the breadth of the claims (see Ex parte Forman, 230 USPQ 546, BPAI, 1986).

The claims are broadly drawn to a pharmaceutical composition comprising SEQ ID NO:6 or 7, or a fusion of SEQ ID NO:3 to 4, or 3 to 5.

The specification teaches the amino acid sequences of SEQ ID NO:6 or 7, or a fusion of SEQ ID NO:3 to 4, or 3 to 5. The specification prophetically asserts a pharmaceutical function for the polynucleotides which encode these polypeptides, as a vaccine or other treatment for cancer, however the specification fails to provide sufficient working examples or guidance to enable the full scope of the claims because no guidance as to the expected mechanism of pharmaceutical function was set forth, no teachings were provided to lead one of skill in the art to believe that the composition had a therapeutic affect, and further, no assays were conducted and no samples tested. The specification teaches only methods of expression of the polypeptide in vitro. No pharmaceutical use was tested or established.

Thus the specification provides no guidance or objective evidence that the instant polynucleotides or any others like them would function as a pharmaceutical . The disclosure of the amino acid sequence of a polypeptide is insufficient support under the first paragraph of 35 U.S.C 112 for claims which encompass pharmaceutical compositions comprising nucleic acids which encode the sequence. The courts have held that:

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based In some way on his teachings, since some improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence, not In compliance with the first paragraph of U.S.C. 112; that paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill In the art; In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement In the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; In cases involving unpredictable factors, such as chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."In re Fisher 427 F.2d 833, 166 USPQ 18 (CCPA 1970)

Furthermore, the claim is brady drawn to an innumerable amount of potential "pharmaceutical compositions", while the specification sets forth no demonstrated pharmaceutical activity, or any evidence that one might be expected. Reasonable correlation

must exist between the scope of the enablement set forth and the scope of the claimed subject matter.

Thus the claims recite methods which encompass the experimental and unpredictable field of in vivo therapy for mammals having a condition characterized by over expression of Her-2 receptor or cancer. The unpredictability of the treatment of human tumors is well established in the art. (see for example: *Osband and Ross, IMMUNOTHERAPY 1990*). An article by *Dermer (BIO/TECHNOLOGY, Vol 12, page 320, 03/1994*) is cited in order to establish the general state of the art and the level of predictability of in vivo therapy . Dermer teaches that "What is significant in culture, for example immunotherapy's killing power or the transformation of 3T3 cells by a mutated proto-oncogene, simply does not have the same significance for cells in vivo."

In the instant case, no assays for pharmaceutical function were conducted. The assertion of pharmaceutical properties is prophetic, with no support or guidance to enable pharmaceutical function.

Therefore, in light of the breadth of the claims, which is large, the unpredictability of the art, which is high, and lack of guidance or working examples, one of ordinary skill in the art would not be enabled to practice the invention commensurate with the scope of the claims.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**anthony.caputa@uspto.gov**].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

July 12, 2001

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